UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,014	03/26/2004	David G. Wild	CV0330 NP	9570

26079 7590 09/15/2010

CONVATEC INC.
100 HEADQUARTERS PARK DRIVE
SKILLMAN, NJ 08558

EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	PAPER NUMBER
3771	
MAIL DATE	DELIVERY MODE
09/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,014	WILD ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 0109*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7,8,10,11,14,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7,8,10,11,14,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 July 2010* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed July 1, 2010. As directed by the amendment, claims 1 has been amended and claims 4, 6, 9, 12-13, and 15-18 are cancelled. Thus, claims 1-3, 5, 7, 8, 10, 11, 14, 19 and 20 are presently pending in this application.

Drawings

2. The drawings filed July 1, 2010 are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

Regarding claim 1 the drawings are incomplete in that they do not show how the conduit connected to the controller is connected to the inflatable sleeve. Moreover, the drawings do not show the gaiter cell, mid-calf cell, and upper cell, which are claimed to consist of only one compartment, wrapping fully around the lower limb.

Regarding claim 2, the "microprocessor control system and a pump" are not shown in the drawings.

Regarding claim 10, the drawings are incomplete in that they do not show a battery or battery compartment on the controller.

Regarding claim 11, the drawings are incomplete in that they do not show a sensor monitoring each cell. However, it is noted that the mid-calf cell shows a sensor (24).

Regarding claim 20, the drawings are incomplete in that they do not show how the conduit attached to the sleeve is attached to the controller to control the flow of fluid in the device.

3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 5, 7-8, 10-11,14 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barak (6,494,852) and Taheri (4,624,244) and further in view of Calderon et al. (6,589,194).

Barak discloses a compression device for the limb of a mobile patient (fig. 1) comprising: an inflatable sleeve (1 of figure 2) adapted to surround the limb; a conduit (4) attached to said sleeve for delivering fluid to said sleeve; and a portable, wearable controller (3 of figure 1) or control unit ((68) and (col. 6, lines 63-67)) attached to said conduit that generates and controls the flow of fluid in the device; wherein the sleeve includes a leg cuff and a foot cuff (figure 2); the leg cuff has three cells on the lower sleeve including: a gaiter cell (2) adapted to wrap around the lower limb in the region closest to the ankle, a mid-calf cell (2) adapted to wrap around the lower limb above the region occupied by the gaiter cell and an upper cell (2) adapted to wrap around the lower limb in the region between the mid-calf cell and the knee (best seen in figure 2), except that it does not explicitly disclose that the sleeve includes consists of a leg cuff and a foot cuff and the leg cuff consists of only three cells and each cell consisting of only one compartment wherein the cells are adapted to wrap fully around the lower limb and wherein each cell is monitored by a sensor and the cells are pressurized to different pressures wherein the upper cell and mid-calf cell alternate in providing compression so that the mid-calf cell provides higher compression when blood is being expelled from the leg and the upper cell provides higher compression to prevent backflow at rest.

However, Barak teaches that “the invention is also intended for use on any body limb such as a foot, a part of a leg” (col. 4, lines 14-15) and “the number of cells in the sleeve can vary, according to the desired treatment” (col. 10, lines 34-35).

Taheri teaches a similar compression device having a sleeve with a leg cuff (27) and a foot cuff (11); the leg cuff consists of three cells: a gaiter cell (B) adapted to

(partially) wrap around the lower limb in the region closest to the ankle, a mid-calf cell (C) adapted to (partially) wrap around the lower limb above the region occupied by the gaiter cell and an upper cell (D) adapted to (partially) wrap around the lower limb in the region between the mid-calf cell and the knee with each cell having only one compartment (bladders inside B, C, and D) for the treatment of diseased leg veins which result in venous hypertension. See: figures 1-3 & col. 1, lines 13-27.

Calderon teaches a leg cuff (figure 1) with cells (2B, 2C & 2D) that wrap fully around the lower limb of a patient. See: col. 2, lines 58-68; col. 3, lines 1-22 and figure 1.

Cariapa et al (5,437,610) teaches a leg compression device with a plurality of pre-fill bladders each containing a separate compression bladder. The pressure sensors are connected to the pre-fill bladders and operate with a pump, valves and a programmable control processor to sequentially inflate the compression bladders proximally on the leg of a patient upon the pressure sensors detecting an increase in pressure.

It would have been obvious to one of ordinary skill in the art at the time of invention was made to limit the Barak device to include only a leg cuff and a foot cuff, as taught by Taheri, Calderon and Cariapa, in order to obtain a device that could be used to treat the lower limb of a person having diseased leg veins and used cells that wrap fully around the lower limb of a patient which would eliminate the need for accessories such as additional wraps and straps and function in response to sensed increases in

pressure to a patients leg thereby only providing treatment based on a patient's sensed needs.

Since Barak already teaches that "various changes, omissions to the form and detail thereof may be made therein" (col. 10, lines 38-40), and Taheri suggest forming a lower leg treatment device, it would have been obvious to one having ordinary skill in the art at the time the invention was made to eliminate the cell of the thigh, to form a lower leg treatment device as taught by Taheri and Calderon. Moreover, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. In re Karlson, 136 USPQ 184.

Regarding claims 2-3, 5, 7, Barak discloses the controller comprises a microprocessor control system (control unit 68, col. 6, lines 63-67) and a pump (pump unit 60, col. 6, lines 22-33); wherein at least one pressure sensor 62/63 or pressure monitoring means (col. 6, lines 37-38) is associated with said sleeve; wherein said sleeve is low profile and discrete (figure 1); said leg and foot cuffs are anatomically shaped to provide compression on those parts of the leg or foot which have the greatest effect on blood flow (best seen in figure 2).

Regarding claims 10-11 and 19, Barak discloses that the controller is battery operated (rechargeable battery pack 67, col. 6, lines 26-28); wherein each cell is monitored by a sensor (62/63 (col. 6, lines 37-38)); and a method of preventing or treating edema or DVT (col. 2, lines 42-49) comprising applying a compression device of claim 1 to the limb of a mobile patient.

Regarding claims 8 and 20, Barak discloses the claimed inventions having all the features except for a sock interposed between the sleeve and the limb. Having a patient wear a sock, when using the device, would be obvious to a skilled artisan. A sock would prevent direct contact of the device with the patient's skin and would therefore prevent direct contamination of the user's skin, and/or the transfer of bodily fluids to, or from, the user to the device. Moreover, a sock would help prevent skin irritation, skin shear and chaffing at the contact surface between the device and the skin of the limb during use.

Regarding claim 14, Barak discloses the claimed inventions having all the features except it is silent regarding the cells may be pressurized to the same or different predetermined pressures. However, Barak teaches (figure 5) a pressure system (50) that has a range of pressure of 50-100 mmHg, and therefore it would have been obvious to one of ordinary skill in the art at the time of invention was made to operate the Bark's pressure system, such that the cells may be pressurized to the same or different predetermined pressures, for the purpose of providing a variety of compression therapy being applied on different body parts of the patient suitable to the patient's condition.

Response to Arguments

6. Applicant's arguments with respect to the objection to the drawings for not showing every feature of the invention specified in the claims have been considered but have not been found persuasive. Therefore, the Objection to the drawing for failing to show every feature of the claims 1, 2, 10, 11 and 20 has been MAINTAINED.

7. Applicant's drawings submitted July 1, 2010 have been entered.

8. Applicant argues in claims 1 and 20, Figure 1 shows that the sleeve 2 is connected to controller 8 by a conduit 10. Conduit 10 can be seen connected to the top of the sleeve in the left hand drawing of the sleeve and connecting to the controller 8 in the right hand drawings; however, the fact that both the sleeve 2 and the controller 8 have conduits 10 id not a demonstration of how the parts are connected together. Applicant should consider adding dotted lines connecting the parts of the device together to show how the device is intended to function. Regarding applicants' argument that Figure 2 shows the gaiter cell, mid-calf cell and upper cell, having one compartment and wrapping fully around the lower limb, the examiner respectfully disagrees. None of the cells are labeled, and from figure 2, it appears there is one cell completely connecting all three regions.

Regarding claim 2, applicant argues that the controller comprises the microprocessor control system and pump (see paragraph 15), and the controller is shown in Figures 1 and 3. Although the examiner agrees that a controller is shown in figures 1 & 3, it is unclear where the microprocessor and the pump reside within the controller and how the microprocessor and pump function together

Regarding claim 10, applicant refers to the specification for providing evidence that the controller is battery powered rechargeable so that it can be recharged on the base unit 12 and that it follows that the battery is inside the controller and the controller is shown in the drawings. Although the examiner agrees that a controller is shown in

figures 1 & 3, it is unclear where the battery resides within the controller and how the controller is operated by the battery, as claimed.

For claim 11, Figure 3 shows the position of the sensors in the cells, numbered 24 and marked on each cell as described in paragraph 37. However, the only cell that shows a marked sensor is the middle cell. The additional circles on the upper and lower portions are not labeled and it is unclear that these are the sensors claimed.

Applicant's arguments with respect to claims 1-3, 5, 7, 8, 10, 11, 14, 19 and 20 have been considered but have not been found convincing. Therefore, the claims have been rejected for the reasons set forth above and the new grounds of rejection have been necessitated by applicant's amendment.

Applicant's arguments against the references individually one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues the device of Barak would not be effective without the thigh cuff and a skilled artisan would believe it was essential to pressurize the thigh cuff; and that when Barak teaches that it can be used on part of a leg, they mean the part of the leg, including the thigh cuff as shown in figures 1 & 2. The examiner respectfully disagrees; however, the obviousness rejection is based upon what a person of ordinary skill in the art would have considered as "a part of a leg." A person having ordinary skill in the art, reading Barak in view of Taheri, Caldeon and Cariapa would not conclude that the device of the combined references, with independently operated cuffs could only be

functionally used and operated as shown in figures 1 & 2 of Barak. An ordinary skilled artisan would readily recognize that the device taught by Barak could be easily modified to treat the lower limb, as taught by Taheri, Calderon and Cariapa with predictable results by simply removing the thigh cuff.

Applicant then argues that Taheri lacks a wearable controller. This feature was taught by Barak in figure 1, part (3) and the examiner specifically pointed to Barak as teaching these components. Thus, although applicant continues to argue the references individually, when the rejection is based upon the combination of references, the combination of the references provides nothing more than an elimination of a thigh cuff, of Barak, to obtain a lower leg treatment device, as taught by Taheri, Calderon and Cariapa.

Regarding applicant's argument that one having ordinary skill in the art would not combine the device of Calderon with that of Barak, the examiner respectfully reminds applicant that Calderon was merely used for its teaching of a leg cuff with cells that wrap fully around the lower limb of a patient, not for its method of pumping or inflating the cuffs.

Thus, the combined references clearly teach the device as claimed and the incentive for modifying the device is to treat the portion of the leg in need of treatment, as determined by one having ordinary skill in the art, and since Taheri teaches a lower leg treatment devices consisting of a leg and a foot cuff, such a modification is clearly within the skill of the art.

Therefore, applicant's arguments have not been found convincing and the obviousness rejection has been MAINTAINED.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Whitney (4,597,384) discloses a compression sleeve with only three cells; McWhorter (5,117,812) is being uses as a teaching reference to show a device that uses individual cells that can be added or eliminated from a leg of a patient in order to provide an easy to use, cheap, method of providing a compression device that has individual cells that can be placed in desired locations on a patient and inflated based on the patient's needs; Hasty (4,013,069) disclosed a compression device that wraps fully around the limb of a patient and has individual cells with independent inflation lines; Arkans (4,574,812) disclosed a compression device that wraps fully around the limb of a patient and has individual cells with independent inflation lines with pressure sensors for detecting thrombus; Hasty (4,091,804) disclosed a compression device that wraps fully around the limb of a patient and has individual cells with independent inflation lines; Tumey et al. (5,991,654) discloses a device for detecting deep vein thrombosis; and Kuiper et al. (6,945,944) disclose compression devices for the lower leg.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767